PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Michael W. Johnson**
Application No.:	**09/880615**
Filed:	**June 13, 2001**
For:	**Stent Drug Delivery System**
Examiner:	**Jermie E. Cozart**
Group Art Unit:	**3726**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-6531-US03

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 23-24, 26-30, 32-33, and 35-40 were finally rejected in an Office Action mailed November 26, 2004. A Notice of Appeal was filed in this case on January 26, 2005. This brief is submitted in accordance with 37 C.F.R. § 41.37:

> *(a)(1) Appellant must file a brief under this section within two months from the date of filing the notice of appeal under §41.31.*
>
> *(2) The brief must be accompanied by the fee set forth in §41.20(b)(2).*
>
> *(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.*

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

> *(c)(1) The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:*

(i) Real Party in Interest

> *(i) Real party in interest. A statement identifying by name the real party in interest.*

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota

Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

No related appeals or interferences are pending.

(iii) Status of claims

(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

Claims 23-24, 26-33, and 35-41 are pending and have been rejected. Of these, claims 31 and 41 have been withdrawn. Claims 1-22, 25, and 34 have been canceled. No claims have been allowed or objected to. The claims that are being appealed are 23-24, 26-30, 32-33, and 35-40.

(iv) Status of amendments

(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.

No amendment was filed subsequent to the final rejection November 26, 2004.

(v) Summary of claimed subject matter

(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

Claims 23-24 and 26-30 pertain to a method for manufacturing a stent from a tube. The required references to the specification and drawings are provided in brackets in the claim summaries below.

The invention, as recited in claims 23-24 and 26-30 provides a novel method by which a stent having at least two different longitudinally spaced regions of different predetermined porosity is manufactured.

According to independent claim 23, a tube is provided [p. 4, ln. 22; p. 8, ln. 26; p. 9, ln. 2].

The tube has at least two different longitudinally spaced regions of different predetermined porosities [p. 7, ln. 10-16; p. 8, ln 5-6; p. 9, ln. 7-9; Fig. 5]. Fig. 5 illustrates these regions in a stent that has been cut from such a tube.

Each region has substantially the same porosity about its circumference [p. 6, ln. 15-19, Fig. 5]. The longitudinally spaced regions are again illustrated in the stent of Fig. 5 and are shown to have substantially the same porosity about a given circumference.

A stent is *then* cut from the tube [p.5, ln. 4-5; p. 8, ln. 14].

According to independent claim 32, a tube is provided [p. 4, ln. 22; p. 8, ln. 26; p. 9, ln. 2]. The tube has at least two different longitudinally spaced regions of different predetermined porosities [p. 7, ln. 10-16; p. 8, ln 5-6; p. 9, ln. 7-9; Fig. 5]. A plurality of openings are cut in the tube to form a stent [p.5, ln. 4-5; p. 8, ln. 14; Fig. 5]. The stent has multiple serpentine bands such that a first band has a different porosity than a second band [p. 6, ln. 19-20; Fig. 5].

(vi) Grounds of Rejection to be Reviewed on Appeal

(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.

Review on appeal is requested of the Examiner's contention that claims 23, 26, 29, and 30 are obvious from Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884).

Review on appeal is also requested of the Examiner's contention that claims 23, 26, 29, 30, 32, 33, and 35-40 are obvious from Richter (U.S. 5,807,404) in view of Solovay (U.S. 5,769,884) and Saunders (5,780,807).

(vii) Argument

(vii) Argument. The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

1. The Examiner Erred in rejecting Claims 23, 24, and 26-30 as obvious over Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884).

Claims 23, 24, and 26-30 have been rejected under 35 USC 103 (a) over Yan (U.S. 5,843,172) in view of Solovay (U.S. 5,769,884). The rejection must be reversed.

To support an obviousness rejection, the cited prior art must specifically suggest the combination as claimed, and it must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. The cited documents themselves must provide some teaching whereby the applicant's combination would have been obvious, again at the time the invention was made. US patent law is replete with cases that illustrate this principle. *See e.g. In re Fine,* 37 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); *In re Kotzab,* 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); and *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir.1999). The Examiner has not made the requisite showing.

Further, as stated in MPEP 2143 and throughout the caselaw, "the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Claims 23, 24 and 26-30 all require the steps of "providing a tube...having at least two different longitudinally spaced regions of different predetermined porosities and each region

having substantially the same porosity about its circumference, and subsequently cutting a stent from the tube".

The Examiner acknowledges that Yan lacks the "providing" step[1] but relies on Solovay to provide the missing teaching. Solovay teaches a stent cover[2] with several regions having different size holes extending therethrough. The Examiner's reliance on Solovay is erroneous for several reasons.

First, there is no motivation to make the proposed combination. Yan teaches uniform porosity and away from areas of different porosity (see col. 4 lns. 58-64) Providing a stent cover which has different size openings in different regions would be contrary to the teachings of uniformity in Yan[3].

Second, even if, for the sake of argument only, there were motivation to combine the two references, the resulting product would be a Yan stent with a Solovay cover. The combination, however, would not result in the stent itself having the recited regions of different porosity at least because neither Solovay nor Yan suggest dispensing with the stent cover and providing the stent itself with different porosites.

Third, even if, for the sake of argument only, there were motivation to modify the Yan stent to provide regions of different porosity, the combination of teachings would, nevertheless, not teach providing a tube with the recited regions of different porosity and subsequently cutting a stent from the tube. Drilling the Solovay holes in the Yan stent prior to cutting the stent pattern would, seeming, be inefficient as portion of the stent that have been

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[1] The Examiner states specifically: Yan, however, does not disclose the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, or a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity.

[2] In the Final Office Action, the Examiner states that "Solovay is analogous art as it is concerined with providing the desired porosity for a stent as is the purpose of applicant's invention. Solovay acheives that purpose by providing a tube that is identical in size and structure to a stent..."
Applicant disagrees – there is no disclosure in Solovay that suggests that the stent cover disclosed therein is capable of functioning as a stent.

[3] The Examiner is in error in asserting that "Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent), and subsequently cutting the stent from the tube."
Yan teaches the importance of uniform porosity along the length of the stent. Such variation in pore size is considered in Yan to be consistent with a uniform porosity. Thus, different sizes of specific pores in the Yan stent does not teach different predetermined physical characteristics.

drilled once in the Solovay step may ultimately be discarded once a stent pattern is cut in the tube.

For at least these reasons, reversal of the rejection under 35 USC §103 is respectfully requested.

Claims 28, 29, and 30 – The cutting step includes forming specific geometries

Claims 28, 29, and 30 are patentable for the reasons discussed above.

Furthermore, in all instances of cutting the stent covering of Solovay it is for the purpose of creating pores and the pores/"openings" are cut into circular holes. Serpentine segments are not formed, and being circular the"openings" are not elongate nor do their widths exceed their length. The combination of Yan and Solovay does not teach these shapes.

2. The Examiner Erred in rejecting Claims 23, 24, 26-30, 32, 33, and 35-40

Claims 23, 24, 26-30, 32, 33, and 35-40 have been rejected under 35 USC 103 (a) over Richter (U.S. 5,807,404) in view of Solovay (U.S. 5,769,884) and Saunders (5,780,807). The rejection must be reversed.

Claims 23, 24, 26-30, 32, 33, and 35-40 - Misconstruction of References, Confusing Assertions, Absence of Motivation

The legal standard for obviousness has been set forth above. The Examiner has not made the requisite showing to support an obviousness rejection.

The combination of Richter, Solovay, and Saunders does not teach or suggest providing a tube having at least two different longitudinally spaced regions of different predetermined porosities and subsequently cutting the tube into a stent. As asserted above, the Examiner's analysis of Solovay is incorrect. The stent cover of Solovay functions properly when placed about a stent and there is no disclosure that it possesses the requisite stent quality of a structure capable of supporting a body lumen. Thus, any cutting performed on the tube in Solovay does not form a stent as claimed in claim 23 or claim 32; instead it forms a stent cover which is then placed about a stent. A skilled person in the art will not look to the stent cover art

to find a method for manufacturing a stent having longitudinally spaced regions of different predetermined porosities.

To the extent that one of ordinary skill in the art were presented with the above-mentioned references, at most one would provide the stent of Richter with the cover of Solovay. This would not, however, render obvious the claimed method. Providing a stent cover of different porosities to an already cut stent is not the same as providing a tube of at least two different longitudinally spaced regions of different predetermined porosities and then cutting a stent from the tube. Nothing in any of the applied references suggest first providing the recited tube of different porosities and then cutting the stent from the tube.

Moreover, even if, for the sake of argument only, one were to take from Solovay a broad teaching that the stent itself may be provided with the different regions of different predetermined porosities, nevertheless, the proposed combination would not teach whether the different porosities should be provided prior to cutting the stent or after cutting the stent. To that end, we note that Solovay teaches laser drilling as one means of providing a stent cover with the desired porosity. Laser drilling prior to cutting the stent would likely result in an inefficient process as portions of the tube that will be discarded are drilled. Thus, in this case, one would not be led to provide a tube with the desired porosities and then cut a stent. Rather one would cut the stent first and then provide it with the different porosities, contrary to the recitations of the claim.

Furthermore, the Examiner often points to the stent produced rather than the method of producing the stent in trying to show obviousness. The first limitation of claims 23 and 32 requires providing a tube having at least two different longitudinally spaced regions of different predetermined porosities; the second limitation is *subsequently* cutting a plurality of openings in the tube to form a stent. The only openings cut in the stent covering of Solovay are the pores themselves. Thus, there is no subsequent cutting to form a stent and the limitation is not met.

In addition, if one were to take the stent cover of Solovay and then cuts it as described in Saunders, the very purpose of the Solovay stent cover would be destroyed; the stent cover would at best now sparsely and intermittently cover the stent and the struts of the stents and would likely interfere with stent expansion as the serpentine portions of the cut stent cover

would become tangled with the serpentine bands of the stent. Thus, one skilled in the art would not use the cutting method of Saunders to cut openings in the porous stent cover of Solovay.

Finally, the Examiner is using the impermissible benefit of hindsight when rejecting claims 23 and 32 for obviousness. The Examiner has not shown any teaching or motivation to combine the references. Motivation to make the combination is lacking in both Richter and Saunders in that neither suggests the desirability of providing a stent with different porosities. Likewise, motivation to make the combination is lacking in Solovay which discloses a stent covering for use on a stent without any suggestion of the porosity being within the stent itself.

The Examiner has not identified a reasonable motivation to combine the Richter, Solovay, and Saunders patents and has not shown how any combination of teachings in these documents could produce the invention of any of claims 23, 24, 26-30, 32, 33, 35-40. For at least these reasons, reversal of the rejection under 35 USC §103 is respectfully requested.

3. Conclusion

The Examiner has not shown motivation to combine the references and even when combined the teachings of these patents still fail to teach or suggest the method of any of the claims 23, 24, 26-30, 32, 33, and 35-40. Claims 23, 24, 26-30, 32, 33, and 35-40 therefore are not obvious from Yan in view of Solovay or from Richter in view of Solovay and Saunders. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: April 21, 2005

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(viii) Claims Appendix

(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.

Claims 1-22. (Canceled)

Claim 23. (Previously presented) A method of manufacturing a stent comprising the steps of: providing a tube, the tube characterized by a longitudinal axis, having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, and subsequently cutting a stent from the tube.

Claim 24. (Previously presented) The method of claim 23 wherein a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal.

Claim 25. (Canceled)

Claim 26. (Previously presented) The method of claim 23 further comprising the step of disposing a treatment agent on the stent.

Claim 27. (Previously presented) The method of claim 23 wherein the stent includes a plurality of serpentine segments extending about the circumference of the stent.

Claim 28. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of serpentine segments which extend about the circumference of the stent.

Claim 29. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of openings which are elongate.

Claim 30. (Previously presented) The method of claim 23 wherein the cutting step includes forming a plurality of openings whose widths exceed their lengths.

Claim 31. (Withdrawn) A stent formed in accordance with the method of claim 23.

Claim 32. (Previously presented) A method of manufacturing a stent comprising the steps of: providing a tube having at least two different longitudinally spaced regions of different predetermined porosities; and subsequently, cutting a plurality of openings in the tube to form a stent having multiple serpentine bands such that a first band has a different porosity than a second band.

Claim 33. (Previously presented) The method of claim 32 wherein a first portion of the tube is made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube is made from a second metal different from the first metal.

Claim 34. (Canceled)

Claim 35. (Previously presented) The method of claim 32 further comprising the step of disposing a treatment agent on the stent.

Claim 36. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment.

Claim 37. (Previously presented) The method of claim 36 wherein the openings which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments.

Claim 38. (Previously presented) The method of claim 37 wherein the first and second side walls are non-parallel to the longitudinal axis of the stent.

Claim 39. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment, the first and second serpentine segments having different physical characteristics.

Claim 40. (Previously presented) The method of claim 32 wherein at least some of the openings are bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Claim 41. (Withdrawn) A stent formed in accordance with the method of claim 32.

(ix) Evidence appendix. An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

Not applicable

(x) Related proceedings appendix. An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

Not applicable

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.